Associate Director,

Biostatistics

Curriculum Vitae

JOAN F. HILTON, Sc.D., M.P.H.

CURRENT POSITION

2003 - 2005 Immune Tolerance Network

San Francisco

Associate Professor of Biostatistics in Residence Department of Epidemiology and Biostatistics University of California, San Francisco 185 Berry Street, Suite 5700, San Francisco, California 94107-1762

EDUCATION

| EDUCATION | ON | |
|---------------------------|---|---|
| 1972 - 1976 $1980 - 1982$ | Spring Hill College, Mobile, Alabama Tulane University, New Orleans, Louisiana | B.S., Biology M.P.H., Epidemiology |
| 1985 - 1987 $1987 - 1990$ | Harvard University, Boston, Massachusetts Harvard University, Boston, Massachusetts | S.M., Biostatistics Sc.D., Biostatistics |
| PRINCIPA | L POSITIONS HELD | |
| 1977 – 1980 | Dep't of Microbiology/Immunology, College of Medicine University of South Alabama, Mobile, Alabama | Research Technician |
| 1981 | Tulane University, New Orleans, Louisiana -Field research conducted in Belize, Central America | Epidemiologist |
| 1982 — 1985 | Mayo Clinic, Rochester, Minnesota -Coordinator, Diethylstilbestrol-Adenosis (DESAD) Project -Mayo Comprehensive Cancer Center | Epidemiologist/ Biostatistician |
| 1986 | Dana-Farber Cancer Institute, Boston, Massachusetts —Eastern Cooperative Oncology Group | Biostatistician |
| 1987 | Department of Surgery, Massachusetts General Hospital Boston, Massachusetts | Biostatistician |
| 1987 – 1989 | Department of Biostatistics, Harvard University, Boston, Massachusetts | Teaching Fellow |
| 1990 — 1997 | Department of Epidemiology and Biostatistics University of California, San Francisco | Assistant Professor |
| ANCILLAR | RY POSITIONS | |
| 1993 | World Health Organization Geneva, Switzerland | Technical Advisor |
| 2003- | Food and Drug Administration Washington, D.C. | Special Government Employee |

HONORS AND AWARDS

| 1980 - 1982 | U.S. Public Health Service Training Grants, Tulane University |
|-------------|---|
| 1985 - 1988 | National Cancer Institute Training Grants, Harvard University |
| 1990 | Student Research Award, Eastern North American Region (ENAR) of the |
| | International Biometric Society |
| 1995 | (Elected) 1997 President, Western North American Region (WNAR) of the |
| | International Biometric Society |
| 1996 | (Elected) 1998 Secretary/Treasurer, Biometrics Section of the ASA |
| 1996 | (Elected) 1999 Program Chair, Statistics in Epidemiology Section of the ASA |
| 2000 | (Appointed) Chair, Local Organizing Committee, Y2K International Biometric Conference |

PROFESSIONAL ACTIVITY

MEMBERSHIP IN AND SERVICE TO PROFESSIONAL ORGANIZATIONS:

American Statistical Association (1988-)

- Student Representative, Boston Chapter (1988-1989)
- Vice President, Boston Chapter (1989-1990)
- Secretary-Treasurer, Biometric Section (1998)
- Program Chair, Section on Statistics in Epidemiology (1998-1999)

International Biometric Society

- Chair, International Biometric Conference (1998-2000)
- Representative to the Medical Sciences Committee of the American Association for the Advancement of Science (2005-2008)
- Eastern North American Region (1989-1990)
- Western North American Region (1990-)
 - Member, Regional Advisory Board (1992-1994), Chair (1994)
 - Program Chair for Regional Meeting (1995)
 - President-elect, President, Past-President (1996-1998)

International Association for Dental Research (1998-2004)

International Society for Clinical Biostatistics (2002-2004)

• Scientific Committee on Statistics in Dentistry

First International Conference on Statistical Modelling in Dentistry

• Planning & Program Committees; Leuven, Belgium, 2004

Society for Clinical Trials (2005+)

• Publications Committee (2005+)

American Association for the Advancement of Science (2005+)

• Medical Sciences Committee (2005-2008)

Invited speaker

REFEREE FOR PROFESSIONAL JOURNALS:

Statistical Journals:

The American Statistician, Australian and New Zealand Journal of Statistics, Biometrical Journal, Biometrics, Controlled Clinical Trials, Journal of the American Statistical Association, The Statistician, Statistics in Medicine

Collaborative Journals:

AIDS, Arthritis & Rheumatism, Cancer Causes & Control, Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, Journal of Clinical Oncology, Oral Diseases, Orofacial Pain, Western Journal of Medicine

INVITED PRESENTATIONS AT PROFESSIONAL MEETINGS AND WORKSHOPS

| INTERNAT | ΓΙΟΝΑL: | |
|----------|--|---|
| 1993 | Second International Workshop: The Oral Manifestations of HIV Infection, San Francisco | Invited speaker, Opening Plenary Session |
| 1993 | Short course sponsored by World Health Organization & Harvard University Association for Diarrheal Disease Research, Cuernavaca, Mexico. | Invited lecturer (Daily \times 5) |
| 1994 | Workshop on Dental Issues in Pediatric HIV/AIDS, University of Toronto, Canada. | Invited lecturer (Daily \times 5) |
| 1997 | International Association for Statistical Computing, Pasadena | Invited speaker |
| 2004 | International Conference on the Future of Statistical Theory, Practice, and Education, Hyderabad, India. | Invited speaker |
| NATIONA | · ; ·· | |
| 1993 | American Public Health Association Annual Meeting, San Francisco | Invited speaker |
| 1998 | Annual meeting of ENAR, International Biometric Society, Pittsburgh | Invited speaker |
| 1998 | Annual Joint Statistical Meeting, Dallas | Invited speaker |
| 2000 | Annual meeting of ENAR, International Biometric Society, Chicago | Invited speaker |
| 2003 | Annual meeting of WNAR, International Biometric Society, Golden, Colorado | Invited speaker |
| 2004 | Society for Clinical Trials, New Orleans, Louisiana | Invited speaker |

2004 Louisiana State University, Baton Rouge, Louisiana

NATIONAL, Continued:

| 2005 | Workshop convened by National Institutes of Health/NIDDK, Bethesda | Invited panelist |
|------|--|--------------------------------------|
| 2005 | Pacific Growth Equities' Life Science Conference, San Francisco | Invited panelist, Plenary Session |

REGIONAL:

| 1996 | Genentech, South San Francisco | Invited speaker |
|------|---|-----------------|
| 1997 | Department of Epidemiology, UC Berkeley | Invited speaker |
| 1997 | Department of Statistics, Stanford University | Invited speaker |
| 1998 | Neyman Lecture Series, Department of Statistics, UC Berkeley | Invited speaker |
| 1999 | San Francisco Bay Area Chapter of the American Statistical Association | Invited speaker |
| 2001 | Genentech, South San Francisco | Invited speaker |
| 2005 | UCLA Department of Biostatistics | Invited speaker |

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

REVIEW PANELS:

| 1992 | National Cancer Institute | Member, Contract Review Panel |
|-------|-----------------------------------|--|
| 1997 | National Cancer Institute | Member, Site Visit Panel |
| 1999 | Hong Kong Research Grants Council | Reviewer, Panel on Biology & Medicine |
| 1999 | Food and Drug Administration | Scientific Review Panel, Office of Women's Health |
| 1999 | National Institute of Dental | Scientific Review Panel |
| | and Craniofacial Research | |
| 2002 | National Cancer Institute | Member, Head & Neck SPORE Review Panel |
| 2003 | National Institutes of Health | Member, Special Emphasis Review Panel |
| 2003+ | Food and Drug Administration | Consultant, Center for Biologics Evaluation and Research |
| 2004+ | Food and Drug Administration | Member, Anti-Infective Drugs Advisory Committee Center for Drug Evaluation and Research |
| 2005 | National Institutes of Health | Member, Study Section for Program Project Applications |

DATA SAFETY MONITORING BOARDS:

1996 Chair, Contact Lens Extended-Wear Study (CLEWS), a National Eye Institutesponsored clinical trial (trial conducted at University of California Berkeley) 2000 Member, Safety Monitoring Committee, Noninvasive Positive Pressure Ventilation for ALS (trial conducted at California Pacific Medical Center)

| DATA | A SAFETY | MONITORING BOARDS, continued: |
|---------|------------|---|
| | 2000+ | Member, Data Safety Monitoring Board, BVAIT Trial (to evaluate the benefit of homocystiene on progression of preintrusive atherosclerosis) (trial conducted at University of Southern California) |
| | 2001 | Member, Data Safety Monitoring Committee, (trial conducted at California Pacific Medical Center) |
| | 2004+ | Chair, Data Safety Monitoring Committee, Multicenter Trial for Maxillofacial Prosthetics (trial conducted at University of Louisville) |
| | 2005+ | Member, Data Safety Monitoring Board, ELITE Trial: Early Versus Late Intervention With Estrogen (trial conducted at University of Southern California) |
| | 2005+ | Member, Data Safety Monitoring Board, ' (trial conducted by ') |
| ОТН | ER PROFE | SSIONAL SERVICE: |
| 0111 | 1999 | Member, Nomination Committee for the Annual Myrto Lefkopoulou |
| | | Distinguished Lecturer, Harvard School of Public Health |
| | 2005-2007 | Member, Harvard School of Public Health, Department of Biostatistics, Alumni Award Committee |
| UNIV | ERSITY | AND PUBLIC SERVICE (PAST FIVE YEARS) |
| UCSI | F CAMPUS | WIDE: |
| 0 0 0 0 | 2002 + | Ad hoc Reviewer, Committee on Advancements and Promotions |
| | 2003 + | Mediator, UCSF Problem Resolution Center |
| | 2005 | Committee for Collaborative Research Evaluation |
| SCH | OOL OF ME | EDICINE: |
| | | 998 Cancer Protocol Review Committee |
| | 1999 + | M.D. with Thesis Committee |
| | 2005 | Search Committee, Department of Obstetrics, Gynecology, and Reproductive Sciences: Faculty Biostatistician |
| SCH | OOL OF DE | ENTISTRY: |
| | 1999 | Search Committee, Department of Dental Public Health |
| DEP | ARTMENT | OF EPIDEMIOLOGY AND BIOSTATISTICS: |
| | 1990 + | Member, Group in Biostatistics |
| | | Grant Development Assistance Program: Author of Statistical Considerations |
| | | for numerous grant proposals |
| | 1995 + | Member, Program in Methods for Longitudinal, Cluster, and Survival Studies |
| | 2001 | Search Committee, Department of Epidemiology and Biostatistics |
| | 2003 - 20 | O04 Search Committee, Department of Epidemiology and Biostatistics: Reclassification of Adjunct faculty into In Residence series |
| PIIR | LIC SERVIC | |
| I UD | 2001+ | · · · · · · · · · · · · · · · · · · · |
| | 2001+2005+ | |
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TEACHING AND MENTORING (PAST FIVE YEARS)

FORMAL TEACHING AT U.C. SAN FRANCISCO:

| | | | | Class |
|-------------|--|--------------|------------------------|-------|
| Year | Course | Contribution | Units | Size |
| 1999 - 2000 | BIO 201: Categorical Data Analysis | 10 lectures | 3 | 5 |
| 2000 | TICR: Module on Clinical Trials | 1 lecture | 3 | 22 |
| 2003 | BIO 226: Current Topics in the Design and Analysis | 5 lectures | 3 | 10 |
| | of Randomized Clinical Trials | • | | |
| 2004 | BIO 226: Current Topics in the Design and Analysis | 5 lectures | 3 | 7 |
| | of Randomized Clinical Trials | | | |
| 2005 | BIO 226: Current Topics in the Design and Analysis | 5 lectures | 3 | 13 |
| | of Randomized Clinical Trials | | | |

INFORMAL TEACHING:

2003 UCSF Division of Biostatistics, Longitudinal Data Program: "Correction for the baseline value in a linear mixed effects model with application to a longitudinal dental experiment"

2004 UCSF Division of Biostatistics, HIV Research Group: "Smoothed AFT model"

2004 UCSF Immune Tolerance Network, Clinical Trials Group: "Study design for new onset diabetes trials"

2005 UCSF Immune Tolerance Network, Clinical Trials Group: "Surrogate markers"

2005 UCSF Immune Tolerance Network, Clinical Trials Group: "Augmenting outcome variables: Composite endpoints and response-adaptive allocation procedures"

PREDOCTORAL STUDENTS SUPERVISED OR MENTORED:

| Dates | $_{ m Name}$ | | Program | Role | Position |
|-------------|--------------|---|---------------------------|--------|----------------------------|
| 2000 - 2004 | 6— | | Epidemiology, UC Berkeley | Mentor | Doctoral candidate |
| 2000 | | | ATCR student | Mentor | Research fellow |
| 2000 | | 1 | ATCR student | Mentor | Research fellow |
| 2002 - 2003 | | | UCSF Biomaterials student | Mentor | Ph.D. candidate |
| 2002 - 2003 | • | | UCSF Biomaterials student | Mentor | Ph.D. candidate |
| 2002 - 2003 | :] | | UCSF Medical student | Mentor | M.D. with Thesis candidate |
| 2003 - 2004 | | | UCSF Medical student | Mentor | M.D. with Thesis candidate |
| 2004 - 2005 |] | | UCSF Medical student | Mentor | M.D. with Thesis candidate |
| 2005 - 2006 | I | | UCSF Medical student | Mentor | M.D. with Thesis candidate |

FELLOWS INFORMALLY MENTORED:

| Dates | $_{ m Name}$ | Program | Role | Position |
|------------------------|--------------|-----------------------------|-----------------------|----------------------|
| 2002 | - | Department of Radiology | Advisor | K23 grant applicant |
| 2004 - 2005 | | Department of Prevention & | Advisor | Post-doctoral fellow |
| | | Restorative Dental Sciences | | K22 grant applicant |

MASTER'S LEVEL STATISTICIANS INFORMALLY MENTORED

| Past: | | |
|-------------|--------|--|
| | | |
| Prese | ent: 1 | |

SUMMARY OF TEACHING HOURS

2003 – 2004: 200 total hours of teaching (including preparation)

Formal class and course teaching hours: 40 (20%)

Informal teaching hours: 60 (30%) Mentoring hours: 100 (50%)

2004 - 2005: 200 total hours of teaching (including preparation)

Formal class and course teaching hours: 40 (20%)

Informal teaching hours: 60 (30%) Mentoring hours: 100 (50%)

2005 – 2006: 200 total anticipated hours of teaching

TEACHING NARRATIVE

I am Course Director for BIO 226: Biostatistical Methods for Clinical Research V, offered by the UCSF Department of Epidemiology & Biostatistics. I developed and first offered this course in 2002-2003, with input from my co-instructor ______, Ph.D. The course covers two broad topics – I teach "Current Topics in the Design & Analysis of Randomized Controlled Trials" and Dr. teaches "An Introduction to Bioinformatics."

The course combines didactic teaching with a "journal club" format. Lectures offered by instructors are supported by current publications from the literature that emphasize biostatistical methods, and software demonstrations provide connections between theory and applications. Each year we update our lectures to reflect current topics in the field. Based on a review of the literature on a topic jointly selected by the instructor and the student, each student presents one seminar of length and style typical of presentations at professional meetings and provides a written summary of this presentation. Thus in addition to targeted biostatistical learning, students learn about journals that carry relevant articles, are encouraged through the exercises to read the literature, and gain experience in concise synthesis and oral and written presentation of the material.

In addition to formal teaching, I mentor medical students in the School of Medicine M.D. with Thesis Program on a one-on-one basis (two past; one present), guide the research efforts of students and post-docs in the School of Dentistry Biomaterials Program (also two past; one present), and provide mentoring to UCSF faculty members through the Division of Biostatistics' Grant Development Assistance Program. I also mentor Master's level statisticians who collaborate on a variety of research studies. Finally, I provide informal lectures and advice to the Immune Tolerance Network's (ITN) Clinical Trials Group, which consists of several physicians and other clinical researchers. Through the ITN involvement I was recently invited to serve as a panelist at an 2005 NIH/NIDDK workshop entitled, "New Onset Diabetes Study: Statistical Comment on the Study Concept." I was pleased to serve on this distinguished panel, moderated by J Neaton, along with statistical colleagues M Espeland, TR Fleming, J Lachin, TA Louis, P Thall, and AA Tsiatis. http://www.niddk.nih.gov/fund/other/trialnet/presentations.htm

PEER-REVIEWED RESEARCH ARTICLES

- Kaufman RH, Noller KL, Adam E, Irwin J, Gray M, Jefferies JA, and Hilton JF. Upper genital tract abnormalities and pregnancy outcome in diethylstilbestrol-exposed progeny. Am J Obstet Gynecol, 1984, 148:973–984.
- 2. Podratz KC, Malkasian GD, Hilton JF, Harris EA, and Gaffey TA. Second-look laparotomy in ovarian cancer: Evaluation of pathologic variables. Am J Obstet Gynecol, 1985, 152:230–238.
- 3. Zincke H, Benson RC Jr, Hilton JF, and Taylor WF. Intrathecal thiotepa and mitomycin C treatment immediately after transurethral resection and later for superficial (stages Ta and Tis) bladder cancer: A prospective, randomized, stratified study with crossover design. *J Urol*, 1985, 134:1110–1114.
- 4. Kooistra KL, Rodriguez M, Powis G, Yaksh TL, Harty GJ, Hilton JF, and Laws ER Jr. Development of experimental models for meningeal neoplasia using intravesical injection of 9L gliosarcoma and Walker 256 carcinosarcoma in the rat. Cancer Res, 1986, 46:317–323.
- Edmonson JH, Krook JE, Hilton JF, Long LJ, Cullinan SA, Everson LK, and Malkasian GD. Ineffectiveness of tamoxifen in advanced endometrial carcinoma after failure of progestin treatment. Cancer Treat Rep, 1986, 70:1019-1020.
- Edmonson JH, Krook JE, Hilton JF, Malkasian GD, Everson LK, Jefferies JA, and Mailliard JA. Randomized phase II studies of cisplatin and a combination of cyclophosphamide-doxorubicin-cisplatin (CAP) in patients with progestin-refractory advanced endometrial carcinoma. Gynecol Oncol, 1987, 28:20–24.
- 7. Smalley SR, Moertel CG, Hilton JF, Weiland LH, Wieand HS, Adson MA, Melton LJ 3rd, and Batts K. Hepatomas in the non-cirrhotic liver. *Cancer*, 1988, 62:1414–1424.
- 8. Tompkins RT, Remensnyder JP, Burke JF, Tompkins DM, Hilton JF, Schoenfeld DA, Behringer GE, Bondoc CC, Briggs SE, and Quinby WC. Significant reductions in mortality for children with burn injuries using prompt eschar excision. *Ann Surg*, 1988, 208:577–585.
- Tompkins RT, Hilton JF, Burke JF, Schoenfeld DA, Hegarty MT, Bondoc CC, Quinby WC, Behringer GE, and Ackroyd FW. Increased survival after massive thermal injuries in adults: Preliminary report using artificial skin. Crit Care Med, 1989, 17:734-740.
- Wrensch MR, Petrakis NL, King EB, Miike R, Mason L, Chew K, Lee MM, Ernster VL, Hilton JF, Schweitzer R, Goodson WH, Hunt TK. Breast cancer incidence in women with abnormal cytology in nipple aspirates of breast fluid. Am J Epidemiol, 1992, 135:130-141.
- 11. Hilton JF and Mehta CR. Power and sample size calculations for exact conditional tests with ordered categorical data. *Biometrics* 1993, 49:609–616.
- 12. Mehta CR and Hilton JF. Exact power of conditional and unconditional tests: Going beyond the 2×2 contingency table. Am Statistician, 1993, 47:91–98.
- 13. Petrakis NL, Lowenstein JM, Wiencke JK, Lee MM, Wrensch MR, King EB, Hilton JF, Miike R. Gross cystic disease fluid protein in nipple aspirates of breast fluid of Asian and non-Asian women. Cancer Epidemiol Biomarkers Prev, 1993, 2:573–579.

- 14. Shafer MA, Hilton JF, Ekstrand M, Keogh J, Gee L, DiGiorgio-Haag L, Shalwitz J, Schachter J. Relationship between drug use and sexual behaviors and the occurrence of sexually transmitted diseases among high-risk male youth. Sex Transm Dis, 1993, 20:307–313.
- 15. Hilton JF, Mehta CR and Patel NR. An algorithm for conducting exact Smirnov tests. *Comput Stat Data Anal*, 1994, 17:353–361.
- 16. Hilton JF, Walsh MM, Masouredis CM, Drues JC, Grady DG, Ernster VL. Planning a spitting tobacco cessation intervention: Identification of beliefs associated with addiction. *Addict Behav*, 1994, 19:381–391.
- 17. Lifson AR, Hilton JF, Westenhouse JL, Canchola AJ, Samuel MC, Katz MH, Buchbinder SP, Hessol NA, Osmond DH, Shiboski S, Lang W, Greenspan D, Greenspan JS. Time from HIV seroconversion to oral candidiasis or hairy leukoplakia among homosexual and bisexual men enrolled in three prospective cohorts. *AIDS*, 1994, 8:73–79.
- 18. Robinson PG, Winkler JR, Palmer G, Westenhouse J, Hilton JF, Greenspan JS. The diagnosis of periodontal diseases associated with HIV infection. *J Periodontol*, 1994, 65:236–243.
- Shiboski CH, Hilton JF, Greenspan D, Westenhouse JL, Derish P, Vranzian K, Lifson AR, Katz MH, Cohen JB, Moss AR, Lyons C, Greenspan JS. HIV-related oral manifestations in two cohorts of women in San Francisco. J Acquir Immune Defic Syndr, 1994, 7:964-971.
- 20. Walsh MM, Hilton JF, Ernster VL, Masouredis CM, Grady DG. Prevalence, patterns, and correlates of spit tobacco use in a college athlete population. *Addict Behav*, 1994, 19:411–427.
- MacPhail LA, Hilton JF, Heinic G, Greenspan D. Direct immunofluorescence vs. culture for detecting HSV in oral ulcers: a comparison. J Am Dent Assoc, 1995, 126:74-78.
- 22. Ramos-Gomez FJ, Hilton JF, Canchola AJ, Greenspan D, Greenspan JS, Maldonado Y. Risk factors for HIV-related orofacial manifestations in children. *Pediatr Dent*, 1996, 18:121–126.
- 23. Hilton JF. The appropriateness of the Wilcoxon test in ordinal data. Stat Med, 1996, 15:631-645.
- MacPhail LA, Hilton JF, Dodd CL, Greenspan D. Prophylaxis with Nystatin pastilles for HIV-associated oral candidiasis. J Acquir Immune Defic Syndr Hum Retrovirol, 1996, 12:470-476.
- 25. Nakagawa M, Stites DP, Farhat S, Judd A, Moscicki A-B, Canchola AJ, Hilton JF, Palefsky JM. T cell proliferative response to human papilloma virus type 16 peptides: Relationship to cervical intraepithelial neoplasia. Clin Diagn Lab Immun, 1996, 3:205-210.
- Shiboski CH, Hilton JF, Neuhaus JM, Canchola AJ, Greenspan D, Cohen JB, Moss AR, Padian NS, Greenspan JS. HIV-related oral manifestations and gender: A longitudinal analysis. Arch Intern Med, 1996, 156:2249-2254.
- Hilton JF, Donegan E, Katz MH, Canchola AJ, Fusaro RE, Greenspan D, Greenspan JS.
 Development of oral lesions in human immunodeficiency virus-infected transfusion recipients and hemophiliacs. Am J Epidemiol, 1997, 145:164-174.
- Gniewek RA, Stites DP, McHugh TM, Hilton JF, Nakagawa M. A comparison of antinuclear antibody testing: immunofluorescence assay versus enzyme immunoassay. Clin Diagn Lab Immun, 1997, 4:185–188.
- Palacio H, Hilton JF, Canchola AJ, Greenspan D. The effect of cigarette smoking on HIV-related oral lesions. J Acquir Immune Defic Syndr Hum Retrovirol, 1997, 14:338–342.

- 30. Masouredis CM, Hilton JF, Grady D, Gee L, Chesney M, Ernster V, Walsh MM. A spit tobacco cessation intervention for college athletes: Three month results. *Adv Dent Res*, 1997, 11:354–359.
- 31. Hilton JF and Gee L. The size and power of the exact bivariate symmetry test. Comput Stat Data Anal, 1997, 26:53-69.
- 32. Hilton JF and Gee L. AS 321 An exact Hollander bivariate symmetry test. Appl Stat J Roy Stat Soc (C), 1997, 46:533-540.
- 33. Mirowski GW, Greenspan D, Hilton JF, Canchola AJ, MacPhail LA, Maurer T, Berger TG, Greenspan JS. Association of cutaneous and oral diseases in HIV-positive patients. *Oral Dis*, 1998, 4:16–21.
- 34. Greenspan JS, De Souza YG, Regezi JA, Daniels TE, Greenspan D, MacPhail LA, Hilton JF. Comparison of cytopathic changes in oral hairy leukoplakia with in situ hybridization for EBV DNA. Oral Dis, 1998, 4:95–99.
- 35. Walsh MM, Hilton JF, Masouredis CM, Grady D, Chesney M, Ernster V. Smokeless tobacco cessation intervention for college athletes: Results after one year. *Am J Public Health*, 1999, 89:228-34.
- 36. Hilton JF. A new asymptotic distribution for Hollander's bivariate symmetry statistic. *Comput Stat Data Anal*, 2000, 32:455-463.
- 37. Hilton JF. Functions of oral candidiasis episodes that are highly prognostic for AIDS. Stat Med, 2000, 19:989-1004.
- 38. Walsh MM, Ellison J, Hilton JF, Chesney M, Ernster V. Spit (smokeless) tobacco use by high school baseball athletes in California. *Tob Control*, 2000, 9(Suppl 2):II32-9.
- Ramos-Gomez FJ, Petru A, Hilton JF, Canchola AJ, Wara D, Greenspan JS. Oral manifestations and dental status in paediatric HIV infection. Int J Paediatr Dent, 2000, 10:3-11.
- 40. Kaplan CP, Hilton JF, Tanjasiri SP, Perez-Stable EJ. The effect of data-collection mode on smoking attitudes and behavior in young African-American and Latina women: Face-to-face interview versus self-administered questionnaire. *Eval Rev*, 2001, 25:454-474.
- 41. Hilton JF, Alves M, Anastos K, Canchola AJ, Cohen M, Delapenha R, Greenspan D, Levine A, MacPhail LA, Micci SJ, Mulligan R, Navazesh M, Phelan J, Tsaknis P. Accuracy of diagnoses of HIV-related oral lesions by medical clinicians: Findings from the Women's Interagency HIV Study. Community Dent Oral Epidemiol, 2001, 29:362–372.
- Shiboski CH, Wilson CM, Greenspan D, Hilton JF, Greenspan JS, Moscicki AB. HIV-related oral manifestations among adolescents in a multicenter cohort study. J Adolesc Health, 2001, 295:109-114.
- 43. Colford JM, Rees JR, Wade TJ, Khalakdina A, Hilton JF, Ergas IJ, Burns S, Benker A, Ma C, Bowen C, Mills DC, Vugia DJ, Juranek DD, Levy DA. Participant blinding and gastrointestinal illness in a randomized, controlled trial of an in-home drinking water intervention. *Emerg Infect Dis*, 2002, 8:29-36.
- 44. Kosel BW, Aweeka FT, Benowitz NL, Shade SB, Hilton JF, Lizak PS, Abrams DI. The effects of cannabinoids on the pharmacokinetics of indinavir and nelfinavir. *AIDS*, 2002, 16:543-550.

- 45. Staninec M, Marshall GW, Hilton JF, Pashley DH, Gansky SA, Marshall SJ, Kinney JH. Ultimate tensile strength of dentin: Evidence for a damage mechanics approach to dentin failure. *J Biomed Mater Res (Appl Biomater)*, 2002, 63:342-345.
- 46. Konishi N, Watanabe LG, Hilton JF, Marshall GW, Marshall SJ, Staninec M. Dentin shear strength: Effect of distance from the pulp. *Dent Mater*, 2002, 18:516-520.
- 47. Oliveira SSA, Marshall SJ, Hilton JF, Marshall GW. Etching kinetics of a self-etching primer. Biomaterials, 2002, 23:4105-4112.
- 48. Gansky SA, Ellison JA, Hilton JF, Kavanagh C, Walsh MM. Oral screening and brief tobacco cessation counseling: A review and original two-year findings. *J Dent Educ*, 2002, 66:1088-98.
- 49. DenBesten PK, Yan Y, Featherstone JDB, Hilton JF, Smith CE, Li W. Effects of fluoride on enamel matrix proteinases. *Arch Oral Biol*, 2002, 47: 763-770.
- 50. Kaplan CP, Zabkiewicz D, McPhee SJ, Nguyen T, Gregorich SE, DiSogra C, Hilton JF, Jenkins C. Health-compromising behaviors among Vietnamese adolescents: The role of education and extra-curricular activities. *J Adolesc Health*, 2003, 32:374-383.
- 51. Zheng L, Hilton JF, Habelitz S, Marshall SJ, Marshall GW. Effect of caries on dentin hardness and elasticity. Eur J Oral Sci, 2003, 111:243-252.
- 52. Oliveira SSA, Pugach MK, Hilton JF, Watanabe LG, Marshall SJ, Marshall GW. The influence of the dentin smear layer on the adhesion of a self-etching primer. *Dent Mater J*, 2003, 19:758-67.
- 53. Walsh MM, Hilton JF, Ellison JA, Gee L, Chesney MA, Tomar S, Ernster VL. Spit (Smokeless) tobacco intervention for high school athletes: Results after 1 year. *Addict Behav*, 2003, 28:1095-1113.
- 54. Abrams DI, Hilton JF, Leiser RJ, Shade SB, Elbiek T, Aweeka FT, Benowitz NL, Bredt BM, Mitchell TM, Mulligan K, Bacchetti P, McCune JM, Schambelan M. Short-term effects of cannabinoids in patients with HIV-1 infection: A randomized, placebo-controlled clinical trial. *Ann Int Med*, 2003, 139:258-66.
- 55. Hilton JF, MacPhail LA, Pascasio L, Sroussi HY, Cheikh B, LaBao ME, Malvin K, Greenspan D, Dodd MJ. Self-care intervention to reduce oral candidiasis recurrences in HIV-seropositive persons: A pilot study. *Community Dent Oral Epidemiol*, 2004, 32:1-11.
- 56. Vo D, Nguyen T, Nguyen P, Hilton JF, Palefsky JM, Ma Y, McPhee SJ. Human papillomavirus and abnormal PAP tests in Vietnamese-American women: A pilot case-control study. J Lower Genital Tract Dis, 2004, 8:217-223.
- 57. Covinsky KE, Hilton JF, Lindquist K, Dudley RA. Development and validation of an index to predict ADL dependence and other adverse outcomes in community-living elders. In press: *Med Care*, 2005.
- 58. Komarek A, Lesaffre E, Hilton JF. Accelerated failure times model for arbitrarily censored data with smoothed error distribution. *J Computational Graphical Statist*, 2005, 14(3):726-745.
- 59. Rees JR, Wade TJ, Levy DA, Colford JM Jr, Hilton JF. Changes in beliefs identify unblinding in randomized controlled trials: A method to meet CONSORT guidelines. *Contemporary Clin Trials*, 2005, 26:25-37.

- Staninec M, Nalla RK, Hilton JF, Ritchie RO, Watanabe LG, Nonomura G, Marshall GW, Marshall SJ. Dentin erosion simulation by cantilever beam fatigue and pH change. J Dent Res, 2005, 84:371-375.
- 61. Weintraub JA*, Hilton JF*, White JM, Hoover C, Wycoff K, Yu L, Larrick J, Featherstone JDB. A plant-derived mutans streptococci antibody clinical trial. *Caries Res*, 2005, 39, 241-250. * Co-first authors.

OTHER PUBLICATIONS

- 1. Mehta CR and Hilton JF. Am Statistician, 1994, 48:175–176. (Letter to the editor)
- 2. Hilton JF. Staging the natural history of HIV disease. In Oral Manifestations of HIV Infection. Proceedings of the Second International Workshop, pp.42 – 48. Greenspan JS, Greenspan D, eds. Chicago: Quintessence Publishers, 1995. (Chapter in book)
- 3. Hilton JF. Case Studies in Biometry, by Lange N, Ryan L, Billard L, Brillinger D, Conquest L, Greenhouse J. J Am Statist Assoc, 1995, 90:800. (Book review)
- 4. Hilton JF. Yates' Continuity Correction. In Encyclopedia of Biostatistics. Armitage P and Colton T, eds. London: John Wiley & Sons, 1997. (One-page entry)
- 5. Fortuin FD and Hilton JF. Statistics from Scratch: An Introduction for Health Care Professionals, by Bowers D. Stat Med, 1997, 16:2932-3. (Book review)

RESEARCH PROGRAM

RESEARCH GRANTS AND ACTIVITIES

I served as Principal Investigator during two NIH funding cycles of the following program project grant (publications 17, 18, 19, 21, 22, 24, 26, 27, 33, 34, 37, 39, 42, and 55 resulted from this funding):

Oral Manifestations of the Acquired Immunodeficiency Syndrome

Funding: NIDR (P01-DE07946), 1992-2005

Program Director: Greenspan; Principal Investigators: (1) Hilton, (2) Agabian, (3) Palefsky

Annual Direct Costs: \$742,650

I wrote a funded site-specific component for the following research grant (publications 29 and 41 resulted from this funding, and item 57 used WIHS data):

Women's Interagency HIV Study

Funding: NIAID (U01-AI34989), 1994–1997

Principal Investigators: Overall, Greenblatt; site-specific component, Hilton

Annual Direct Costs: \$1,356,219

I have contributed as a Co-investigator to a large number of funded research grant applications; recent projects are described below. (Please see also FISCAL RESOURCES, below.)

OBSERVATIONAL EPIDEMIOLOGICAL STUDIES

- 1. For 10 years I served as P.I. of "Project 1: Epidemiology of the Oral Manifestations of HIV." This longitudinal epidemiologic study was part of an NIH-sponsored Program Project that most recently focused on changes in the epidemiology of oral lesions in reaction to HAART use. Most analyses for this project used observational data; data also came from randomized controlled trials. Our final publication was Hilton JF, MacPhail LA, et al. "Self-care intervention to reduce oral candidiasis recurrences in HIV-seropositive persons: A pilot study," Community Dent Oral Epidemiol 2004, 32:1-11.
- 2. Recently I have been collaborating with biostatistical colleagues on analysis methods for HIV research. To this end, I co-authored a paper with A Komarek and E Lesaffre at Catholic University in Leuven, Belgium. "Accelerated failure times model for arbitrarily censored data with smoothed error distribution" (in press).

RANDOMIZED CONTROLLED TRIALS

- 1. I am the sole biostatistician at the coordinating center of the Immune Tolerance Network (ITN), which currently sponsors approximately 20 phase I-III trials internationally http://www.immunetolerance.org/. My role is to provide study designs for trials being developed, and to provide general statistical guidance (e.g., DSMB advice). Biostatisticians at a contract research organization support approved trials once enrollment begins.
 - I gave an invited lecture about the ITN to the Society for Clinical Trials in a session entitled, "New Frontiers in Clinical Trials" (May 2004).
 - I served as a statistical panelist at a workshop to discuss optimal study designs for new onset type-I diabetes mellitus (March 2005).

| | I serve as study biostatistician for the randomized double-blind trial, ," led by and colleagues at |
|----|---|
| 3. | I serve as study biostatistician for the randomized double-blind trial of "The efficacy of |
| | and disease," led by ' |

DESIGNED EXPERIMENTS

My collaboration with a large team of material scientists (PIs, SJ and GW Marshall) focuses on a wide range of basic science questions, in both mice and humans. Our most recent publication, Staninec et al, 2005, was published in dentistry's most prestigious journal, *The Journal of Dental Research*. Several additional projects are currently under analysis for this group.

FIVE MOST IMPORTANT PUBLICATIONS (PAST 5 YEARS)

(1) Hilton JF. A new asymptotic distribution for Hollander's bivariate symmetry statistic. *Comput Stat Data Anal*, 2000, 32:455-463.

This was the third in a series of papers about Hollander's test. The first two characterized its exact size as a function of intra-pair correlation and power as a function of location and scale effects, and provided the software needed to carry out the exact test. The third paper proposed an alternative to the existing asymptotic test. It showed that the size and power characteristics of the existing test are extremely poor (it never rejects H_0 at n > 10!), but those of the new test are good, making it a convenient approximation to the exact test.

(2) Hilton JF. Functions of oral candidiasis episodes that are highly prognostic for AIDS. Stat Med, 2000, 19:989-1004.

This paper evaluates 7 functions of candidiasis lesions that one might analyze when assessing their prognostic value, and finds two that are far more powerful that the others. This finding allows researchers to collect candidiasis data so as to optimize their inherent power. This paper reflects my long-term collaborative research on HIV-related oral lesions.

(3) Hilton JF et al. Accuracy of diagnoses of HIV-related oral lesions by medical clinicians: Findings from the Women's Interagency HIV Study. Community Dent Oral Epidemiol, 2001, 29:362–372.

We found that, relative to dental clinicians, medical clinicians recognize the presence of HIV-related oral abnormalities in 40% to 75% of cases, but less often describe them accurately. We believe that this low sensitivity implies that the true associations of specific oral lesions with other HIV phenomena, such as time till AIDS, must be stronger than the literature suggests.

Like paper (2), this paper reflects my long-term collaborative research on oral lesions. As the project PI, I seek not only to provide biostatistical support for clinical research but also to advance this field methodologically.

(4) Abrams DI, Hilton JF, et al. Short-term effects of cannabinoids on in patients with Human Immunodeficiency Virus-1 infection: Results of a randomized controlled clinical trial. *Ann Int Med*, 2003, 139:258-66.

This project presented a number of challenges that were rewarding to solve. First, three [safety] outcomes were analyzed on the log scale. Anticipating that audience interpretation of this scale might vary by outcome, we reported one treatment effect as a mean difference on the log 10 scale (HIV RNA level) and the others as ratios of geometric means (CD4 and CD8 counts). For the latter estimates we generated bootstrapped rather than parametric confidence intervals. Secondly, some patients did not stabilize during the 4-day run-in period and thus within-group treatment effects were modeled as nonlinear functions of time. Finally, the small sample size made it difficult to distinguish between treatment effects and confounders, requiring cautious interpretation.

(5) Komarek A, Lesaffre E, Hilton JF. Accelerated failure times model for arbitrarily censored data with smoothed error distribution. *J Computational Graphical Statist*, 2005, 14(3):726-745.

We develop a procedure to estimate model parameters in an accelerated failure times model (AFT) with an unspecified error distribution and any type of censoring. Our approach uses smoothing techniques (B-splines with penalties replaced by normal densities) to express the density of the error distribution. It estimates spline coefficients and any number of regression parameters via penalized maximum likelihood.

RESEARCH SUPPORT (1999-2004)

Randomized Controlled Trials:

Collaborative Network for Clinical Research on Immune Tolerance

Funding: NIAID (N01 AI15416), 2001-2006

Principal Investigator: Bluestone; Annual Direct Costs: \$19,466,930

A Blinded Randomized Trial of Home Water Filtration

Funding: CDC, via the Western Consortium for Public Health; 1997-1999

Principal Investigators: Overall, Reingold & Colford; UCSF subcontract, Hilton

Annual Direct Costs: \$11,513

Randomized Trial of Tapwater in the Elderly

Funding: NIA (R01-AG16634), 2000-2005

Principal Investigator: Colford; Annual Direct Costs: \$503,374

A Smokeless Tobacco Cessation Program: Rural High School Athletes

Funding: NCI (R01-CA67654), 1995-1999

Principal Investigator: Walsh; Annual Direct Costs: \$229,312

Self-care Intervention to Prevent Oral Candidiasis

Funding: NINR (R01-NR04396), 1996-2004 effort ended 6/01 Principal Investigator: MacPhail; Annual Direct Costs: \$205,769

A Novel Therapy for Dental Caries

Funding: SBIR, 1996-2000

Principal Investigators: Overall, Larrick; UCSF subcontract, Weintraub

Annual Direct Costs: \$247,491

Short-term Effects of Cannabinoids in HIV Patients

Funding: NIDA (R01-DA11607), 1997-2000

Principal Investigator: Abrams; Annual Direct Costs: \$963,384

Marijuana for treatment of HIV-related peripheral neuropathy

Funding: UC Center for Medicinal Cannabis Research (C00-SF-101), 2001-2004

Principal Investigator: — Annual Direct Costs: \$

Marijuana in combination with opioids for treatment of cancer pain

Funding: UC Center for Medicinal Cannabis Research (C00-SF-108), 2002-2003

Principal Investigator: —— Annual Direct Costs: \$'———

Once-daily Aminoglycoside in Cystic Fibrosis

Funding: Cystic Fibrosis Foundation, 1999-2002

Principal Investigator: — Annual Direct Costs: \$

Expanding Preventive Therapy for Tuberculous Infection

Funding: NIAID (K08 AI01549), 1998-2003

Principal Investigator: Jasmer; Annual Direct Costs: \$107,750

Observational Epidemiologic Studies

Statistical Methods for Complex HIV Cohort Studies

Funding: NIAID (R01 AI55085); 2002-2005

Principal Investigator: Bacchetti; Annual Direct Costs: \$441,452

Positive Choice: Prevention for Positive Health Funding: NIDA (R01 DA015016); 2002-2006

Principal Investigator: Gerbert; Annual Direct Costs: \$437,358

Oral Manifestations of the Acquired Immunodeficiency Syndrome

Funding: NIDR (P01-DE07946), 1992-2005

Program Director: Greenspan; Annual Direct Costs: \$742,650

Prognosis/Risk Indices for Function/Mortality in Elders

Funding: NIA (R01 AG19827); 2001-2004

Principal Investigator: Covinsky; Annual Direct Costs: \$100,000

Smoking Initiation among Chinese and Vietnamese Adolescents
Funding: Tobacco-Related Disease Research Program, 1997-2000
Principal Investigator: , Annual Direct Costs: \$

 ${\it Cancer-related behaviors of \ Vietnamese \ Youth}$

Funding: American Cancer Society, 1997-2000

Principal Investigator: —— Annual Direct Costs: \$——

Basic Science Research

Dentin Structure, Demineralization, and Shrinkage

Funding: NIDCR (R01-DE11526), 1995-2001

Principal Investigator: Marshall, G.W.; Annual Direct Costs: \$223,881

Characterization and Modification of Dental Hard Tissues

Funding: NIDCR (P01-DE09859), 1996-2007

Principal Investigator: Marshall, S.J.; Annual Direct Costs: \$834,149

DEJ: Biomimetic Model for Material-Tissue Interfaces

Funding: NIDCR (R01-DE13029), 1998-2003

Principal Investigator: Marshall, S.J.; Annual Direct Costs: \$200,000

Pain and Neural Dysfunction from Acute Herpes Zoster

Funding: NINDS (R01 NS39521), 2000-2004

Principal Investigator: Rowbotham; Annual Direct Costs: \$150,265

Mechanisms of Pain and Analgesia

Funding: NINDS (P50 NS021445), 1985-2004

Principal Investigator: Fields/Rowbotham; Annual Direct Costs: \$140,979

Mechanisms of Ischemic Neonatal Brain Injury Funding: NINDS (P50-NS35902), 1997-2002

Principal Investigator: Ferriero; Annual Direct Costs: \$731,439